

SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety

June 17, 2015—Contemporary Issues in Risk Assessment

FDA, College Park, Maryland • Live Webcast

Contemporary Issues in Risk Assessment June 17, 2015

Colloquium Overview

The National Academies of Sciences committee that produced a report "Science and Decisions: Advancing Risk Assessment" (NRC, 2009) recommended that "risk assessment should be viewed as a method for evaluating the relative merits of various options for managing risk rather than an end in itself." How can the federal government best accomplish this goal? This session will focus on recent improvements in the practice of human health assessments. Exciting advances in the methods and best practices, consistent with the advice from the National Academies, have been made in the recent years and implemented by a number of stakeholders. Specifically, this session will cover the lessons learned from (1) problem formulation and protocol development in chemical-specific human health assessments; (2) evidence identification and transparent criteria for inclusion and exclusion of the individual studies in the assessment; (3) harmonization of the cancer and non-cancer dose-response assessments; and (4) the use of the mechanistic data in support of human health assessments. Overall, the learning objective for this session is to demonstrate tangible examples of the implementation of the best practices in risk assessment to illustrate how the field is evolving to meet the needs of various stakeholders.

Schedule

| 8:00 AM-8:15 AM | Badge Pick Up |
|-------------------|--|
| 8:15 AM-8:25 AM | US FDA Welcome and Overview Suzanne Fitzpatrick, Colloquium Chair, US FDA Center for Food Safety and Applied Nutrition, College Park, MD |
| 8:25 AM-8:30 AM | Welcome from SOT |
| | Ivan Rusyn, Texas A&M University, College Station, TX |
| 8:30 AM-9:15 AM | Problem Formulation and Scoping for Human Health Assessments |
| | Juleen Lam, University of California San Francisco, San Francisco, CA |
| 9:15 AM-10:00 AM | Identification and Selection of the Evidence Base for Human Health Assessments Kathryn Guyton, International Agency for Research on Cancer Monographs Programme, |
| | Lyon, France |
| 10:00 AM-10:15 AM | Break |
| 10:15 AM-11:00 AM | Harmonizing Dose-Response Assessment for Cancer and Non-cancer Endpoints in Human Health Assessments |
| | Weihsueh Chiu, Texas A&M University, College Station, TX |
| 11:00 AM-11:45 AM | The Use of the Mechanistic Evidence in Human Health Assessments |
| | J. Vincent Cogliano (by webinar), US EPA, Crystal City, VA |
| 11:45 AM-12:30 PM | Roundtable Discussion |
| | Ivan Rusyn, Moderator |
| | All Speakers |
| | All speakers |
| 12:45 | Informal lunch for speakers and FDA employees |